

REPORT FOR RELEASE

Meeting of 15-16 February 2007

CMD(v) continues a case-by-case approach for generic applications, where the generic has more indications, more species or shorter withdrawal periods than the reference product in a member state.

Member states endorsed the principle that a generic may have a different SPC from the reference product. An additional claim may be substantiated by data provided by the applicant. Where an additional claim is based on the originator product authorised in the reference member state, member states differ in the extent they wish to assess supporting data of the originator product.

CMD(v) has requested the Heads of Medicines Agencies for guidance on:

- harmonising the national policies for dealing with additional claims for generics;
- the legal pathway the marketing authorisation holder of a originator product can follow to keep parity with the generic.

Pending guidance, the case-by-case approach will be continued. Applicants are advised to discuss an application with the reference member state and concerned member state(s) before submission.

Best practice guide

A best practice guide for countries that act as reference member state in a mutual recognition or decentralised procedure was adopted. The guide is a new step in enhancing harmonisation and efficiency in the conduct of procedures. It will be published on the CMD(v) website.

New members

CMD(v) welcomed two new members: Renate Kuske from Latvia, replacing Valda Sejane, and Lilia-Marina Guerreiro Louzeiro from Portugal, succeeding Margarida Alves. The published list of CMD(v) members will be updated consequently.

New website

As from 28 February 2007 CMD(v) will change website. The new address is www.hma.eu. Documents available on the old website will be moved and from now only the new website will be updated. The management of the website has been transferred from France to Germany. In the near future the CMD(v) secretariat will maintain, however, the CMD(v) part. France will manage the VMR Index, which contains SPC texts, for one further year.

Product discussion

Two products reached day 198 of the decentralised procedure and 11 products reached day 78 of the mutual recognition procedure in February. Out of these 9 products were discussed at the meeting. CMD(v) also discussed one referral at day 53 of the 60 day procedure.

On another referral, agreement was reached before the meeting. Paracillin vet (Intervet) was referred to CMD(v), following the mutual recognition procedure, by France and Germany due to concerns over the efficacy of the (reference) product.

	MRP	DCP	Referrals
<i>procedures</i>	15	2	2
products	11	2	2
immunological	2	0	1
pharmaceutical	9	2	1
discussed	8	1	1

It was noted that following the January meeting agreement was reached on all 6 products by the end of the mutual recognition or decentralised procedure.

Information

CMD(v) documents are available on www.hma.eu.

For further information, please contact the secretariat at the European Medicines Agency, for the attention of Wim Riepma, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK wim.riepma@emea.europa.eu